REMARKS

The foregoing amendments to the claims eliminate multiple dependencies and remove a claim which is not in proper form under U.S. practice. An alternative limitation in claim 6 has been made the subject of new dependent claim 9.

New claims 10-15 are product claims.

The term "Carbopol" is a registered trademark for a family of resins which are high molecular weigh, allylpentaerythritol-crosslinked, acrylic acid-based polymers modified with C_{10}-C_{30} alkyl acrylates. These resins have been given the generic name "carbomer" by the USP-NF, British Pharmacopoeia, United States Adopted Names Council (USAN) and Cosmetic, Toiletries and Fragrance Association (CTFA). Thus, the generic name of Carbopol 940 is carbomer 940. The specification and claims have been amended to use the generic name.

It is believed that the foregoing amendment introduces no new matter into the application, and it is therefore requested that the amendment be entered.

Respectfully submitted,

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Bakulesh Khamar
SERIAL NO.: 09/868,075
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DOCKET NO.: 8076
FOR: THE PROCESS FOR MANUFACTURING FORMULATION OF TOPICAL BETA BLOCKERS WITH IMPROVED EFFICACY.

U.S. National Stage of
International Application PCT/IB99/00378
IA Filing Date: 01 March 1999

Box PCT
Assistant Commissioner of Patents
Washington, D.C. 20231

September 14, 2001

Sir:

SPECIFICATION PARAGRAPHS AND CLAIMS MARKED TO SHOW CHANGES FOLLOWING PRELIMINARY AMENDMENT

SPECIFICATION

———Beta-blockers are known to reduce I.O.P. mainly by reduction in aqueous secretion. This reduction in aqueous secretion is dose dependent. However, increasing the dosage beyond a point does not improve its capacity to reduce I.O.P. For timolol, levobunolol and ~~Betaxalol~~ betaxolol it is achieved at 0.5% concentration, for carteolol it is 1%, and for metipranolol it is 0.3%. Increasing concentration beyond this does not result in further reduction in I.O.P.

———Beta-blockers described above can be timolol 0.5%, ~~Betaxolol 0.5%, Levobunolol 0.5%, Cartelol 1.0%, metipruanolol~~

~~0.3%~~betaxolol 0.5%, levobunolol 0.5%, carteolol 1.0%, metipranolol 0.3%, or any other Beta-blocker which can reduce I.O.P in a therapeutic concentration.

~~Carbopol can be carbopol 940,932~~Carbopol is a registered trademark for a family of resins which have been given the generic name "carbomer." The carbomer can be Carbopol 940, 932, 970 or others which ~~forms~~form a gel in aqueous solution. The concentration of ~~carbopol in~~carbomer in the final formulation can be from 0.5% to 5%.

CLAIMS

1. (amended) A process of manufacturing ~~of~~ a formulation of topical ~~beta~~Beta blockers with improved efficacy comprising the following steps:

i) a. ~~Making~~making aqueous solution of Beta-blocker with or without physiologically acceptable excipients, buffers and ~~preservatives.~~preservatives;

b. ~~Making~~making a gel of known gel forming substance with or without physiologically acceptable excipients buffers and preservatives in a separate ~~vessel.~~vessel;

ii) ~~Adding~~adding aqueous solution of Beta-blockers at step i (a) into a prepared gel of step i (b) while stirring ~~slowly.~~slowly; and

iii) ~~Adjusting~~adjusting the pH and volume before finally autoclaving and packaging.

2. ~~A process as claimed in claim 1 wherein Beta-blockers can be selected from~~ (amended) The process of claim 1 wherein the Beta-blockers are selected from the

group of topical Beta-blockers used to reduce intraocular ~~pressure, e. g.~~pressure consisting of Timolol, Betaxolol, Carteolol, ~~Metipranalol.~~and Metipranolol.

3. ~~A process as claimed in claim 1 & 2 wherein gel forming agent can be carbopol.~~ (amended) The process of claim 1 wherein the gel forming agent is a carbomer.

4. ~~A process as in claim 1 to 3 wherein concentration of carbopol can be~~ (amended) The process of claim 3 wherein the concentration of carbomer is from 0.5% to 5%.

5. ~~A process as claimed in claim 1 to 4~~ (amended) The process of claim 1 in which physiologically acceptable buffers, excipients and preservatives are used.

6. ~~A process as claimed in claim 1 to 5 wherein pH of~~ (amended) The process of claim 1 wherein the pH of the formulation is finally adjusted to between 6.0 to 8.0 ~~preferably between 6.5 and 7.5~~.

7. ~~A process as claimed in claim 1 to 6 wherein~~ (amended) The process of claim 1 wherein the formulation is autoclaved before packaging.